DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 20, 2015

SurgiQuest, Inc.
Mr. Daniel Donovan
Sr. Director, Quality & Regulatory Affairs
333 Quarry Road
Milford, Connecticut 06460

Re: K143404
Trade/Device Name: SurgiQuest AirSeal iFS System
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: Class II
Product Code: HIF, GCJ
Dated: February 4, 2014
Received: February 25, 2015

Dear Mr. Donovan,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143404

Device Name
SurgiQuest AirSeal® iFS System

Indications for Use *(Describe)*
The SurgiQuest AirSeal® iFS System is intended for use in diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas, to establish and maintain a path of entry for endoscopic instruments and to evacuate surgical smoke. It is indicated to facilitate the use of various laparoscopic instruments by filling the abdominal cavity with gas to distend it, by creating and maintaining a gas sealed obstruction-free instrument path and by evacuating surgical smoke. This instrument is used to insufflate the rectum and colon to facilitate endoscopic observation, diagnosis and treatment. The trocar of the AirSeal® iFS System is indicated for use with or without visualization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY OF SAFETY & EFFECTIVENESS
(Content in accordance with 21 CFR §807.92)

Submitter: SurgiQuest, Inc.
333 Quarry Road
Milford, CT 06460

Contact Person: Daniel Donovan
Sr. Director., Quality & Regulatory Affairs

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Date Prepared: November 14, 2014

Trade Name: Trade Name: AirSeal® iFS System
(Original FDA Clearance as "SurgiQuest AirSeal® Optical Trocar & Cannula System with integrated Insufflator DPIS 2000", [k103692].

Common Name: Disposable Endoscopic Trocar and Cannula;
Carbon Dioxide Insufflator for Laparoscopy

Classification Name: Endoscope and accessories under 21 C.F.R. 876.1500;
Laparoscopic Insufflator under 21 C.F.R. 884.1730

Regulatory Class: II

Product Code: GCJ and HIF

Predicate Devices: "SurgiQuest AirSeal® Optical Trocar & Cannula System with integrated Insufflator DPIS 2000"
SurgiQuest, Inc., k103692
(Primary Predicate)

"Olympus High Flow Insufflation Unit UHI-4"
Olympus Medical Systems, Corp., k122180
(Second Predicate)

Device Description:

The SurgiQuest AirSeal® iFS System (*cleared as AirSeal® Optical Trocar & Cannula System with integrated Insufflator DPIS 2000*) consists of the following major components: (1) a trocar, (2) a cannula, (3) tube sets, and (4) a micro-processor controlled insufflation, recirculation and filtration unit (the "AirSeal® iFS"). The cannula, trocar and tube sets are sterile, single-use products.

The AirSeal® iFS System is an active medical device, non-sterile and reusable and is intended to insufflate a body cavity. The AirSeal® iFS System is designed to function in one of three (3) separate modes of operation: (a) Insufflation Mode; (b) AirSeal Mode; or (c) Smoke Evacuation Mode. The device contains software. The device is designed for use in hospitals and clinics.

The AirSeal® iFS System has been developed in accordance with 21 CFR 820, ISO 13485:2012 & ISO 14971:2012 is tested in accordance with IEC 60601-1, General Requirements for Medical Electrical Equipment - Part 1: General Requirements for Safety and IEC60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

Gamma sterility validation for sterile modules has been performed in accordance with ISO 11137 Sterilization of health care products – Radiation, Part 1 – Part 3 and Sterilization of Healthcare Products: Radiation Sterilization - Substantiation of 25kGY as a Sterilization Dose - Method VD Max. ETO sterility validation has been performed ISO 11135-1, Sterilization of health care products –Ethylene Oxide – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices; and ISO 10993-7, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals. Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) data shows that the limit of EO < 5 mg / 10 days and ECH < 5 mg / 10 days that remain on the tube set will not be exceeded. A sterility assurance level (SAL) is $\leq 10^{-6}$ achieved.

Package and product integrity were tested in accordance with ISO11607-1, Packaging for Terminally Sterilized Medical Devices and ASTM-F-1980-02, Standard for Accelerated Aging of Sterile Medical Device Packages.

ISO 11137 -2, Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose.

Finally, biocompatibility testing has been performed on the cannula, the optical trocar, the blunt tipped trocar including fixation device and the AirSeal® filtered tube sets in accordance with ISO 10993-5, Biological Evaluation of Medical Devices – Part 5: Tests for InVitro Cytotoxicity; ISO 10993-10, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed Type Hypersensitivity,; and ISO 10993-5:2009, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Material.

Intended Use:

The AirSeal® iFS System is intended for use in diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas, to establish and maintain a path of entry for endoscopic instruments and to evacuate surgical smoke.

Indications for Use: The SurgiQuest AirSeal® iFS System is intended for use in diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas, to establish and maintain a path of entry for endoscopic instruments and to evacuate surgical smoke. It is indicated to facilitate the use of various laparoscopic instruments by filling the abdominal cavity with gas to distend it, by creating and maintaining a gas sealed obstruction-free instrument path and by evacuating surgical smoke. This instrument is used to insufflate the rectum and colon to facilitate endoscopic observation, diagnosis and treatment. The trocar of the AirSeal® iFS System is indicated for use with or without visualization.

The Indications for Use is not identical to the Predicate device in that the subject device (which is also the primary predicate) is not indicated for surgical harvesting of the saphenous vein. The indication change is to add only the diagnosis and treatment of the rectum and colon. These differences in Indication for Use do not affect the safety and effectiveness or alter the therapeutic use of the device in the indication for trans-anal minimally invasive surgery.

Substantial Equivalence:

The AirSeal® iFS System is substantially equivalent to the AirSeal® DPIS 2000 (k103692) and the Olympus High Flow Insufflation Unit UHI-4 insufflator (k122180). The proposed device has similar technological characteristics (operating principle, electrical characteristics, mechanical characteristics, communication characteristics, material). The device has the same intended use as the Predicate Device. In addition, the AirSeal® iFS System and the Predicate Devices use the same or similar basic operating principles, i.e., they function to distend a cavity to facilitate minimally invasive surgery. (Note: the AirSeal® iFS System is unchanged in intended use and operating principle) Bench test results demonstrate that the AirSeal® iFS System is safe and effective in creating and maintaining pneumorectum.

An engineering in-vitro bench test was conducted to compare the performance of the subject (The AirSeal® iFS System) and the predicate (Olympus High Flow Insufflation Unit UHI-4) insufflator devices in a small cavity. (Engineering Test No. 0206151530_01). The test demonstrates conclusively that there is substantial equivalence in performance.